

REMARKS

In view of the following remarks, the Examiner is requested to withdraw the rejections and allow Claims 33-40, 42-45, 47-50 and 53-54, the only claims pending and under examination in this application.

Claims 33, 40, 48, 50 and 53 have been amended. Claim 33 has been amended to incorporate the element of Claim 41. Claim 48 has been amended to incorporate the elements of Claims 50-53. Consequently Claims 41, 51 and 52 have been cancelled. Claim 40 has been amended to clarify the claim language and Claim 53 has been amended to change its dependency. Claim 50 is also amended and is now directed to a calcium phosphate cement composition. Support for this amendment can be found throughout the specification and Claims as originally filed. For instance, page 4, lines 27-28. Accordingly, no new matter has been added.

As no new matter is added by way of these amendments, entry thereof is respectfully requested.

Claim Rejections - 35 U.S.C. § 102

Claims 48 and 49 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Tepic (U.S. Patent No. 4,463,875).

Claim 48 has been amended. Claim 48 as amended is directed to a kit for using a bone defect filling cement. The kit includes a cement composition introduction element, a vibratory element and an implantable hardware device, wherein the hardware device is a plate, a wire, or a screw. Claim 49 depends from Claim 48 and incorporates all the elements recited therein.

The Office asserts that Tepic discloses every element of Claims 48 and 49.

The Applicants respectfully disagree to the extent that this rejection may be held to apply to the claims as amended. As amended Claims 48 and 49 recite an implantable hardware device, wherein the hardware device is a plate, a wire, or a screw. Nowhere does Tepic teach an implantable hardware device that is a plate, a wire or a screw. Because Tepic does not teach every element of the rejected claims, Tepic fails to anticipate the claimed invention. Therefore, the Applicants respectfully request that the 35 U.S.C. § 102(b) rejection of Claims 48 and 49 be withdrawn.

Claim Rejections - 35 U.S.C. § 103

Claims 33-42, 44-45, 47-50 and 52-54 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Li *et al.* (U.S. Patent No. 6,610,079) in view of Tepic (U.S. Patent No. 4,463,875) and Ison *et al.* (U.S. Patent No. 5,496,399).

As set forth above, Claim 33 has been amended to incorporate the feature of Claim 41. Claim 33 is directed to a method of introducing a calcium phosphate cement composition into a target bone site. The method includes positioning a hardware device at the target bone site and delivering the calcium phosphate cement composition to the target bone site to produce a composite fixation structure of the hardware device and the cement at said target site. A feature of Claim 33, as amended, is that the cement is vibrated as it is delivered to the target bone site in a manner such that penetration of the cement into the target bone site stops substantially simultaneously with cessation of vibration. This element of the claimed invention is important, as it allows one to use both high viscosity and low viscosity cements and provides high control over their delivery and therefore reduces risk of the occurrence of emboli.

In rendering this rejection, the Office acknowledges that Li is deficient in that it fails to teach or suggest delivering a calcium phosphate cement by vibration of the cement as it is being delivered to the target bone site. Accordingly, the Office relies upon Tepic and Ison to remedy the deficiencies of Li.

Tepic, however, is directed to a device and a method of using the device for mixing and applying a two-component cement to a target site. The device disclosed in Tepic is set forth below.

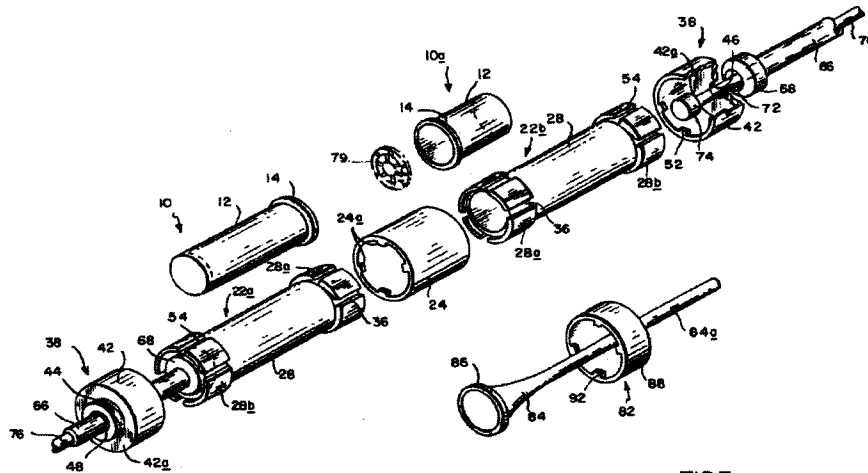


FIG.3

An operator mixes the cement by applying pressure to or retracting alternate piston rods (76) of the mixing assembly. See column 8, lines 1 to 15. Once the cement is mixed one piston rod is replaced with a delivery needle and the other piston rod is extended to collapse the compartments and deliver the cement. See column 4, lines 36 to 48.

The Applicants contend that nowhere does Tepic teach or suggest that the cement to be delivered is vibrated in a manner such that penetration of the cement into the target bone site stops substantially simultaneously with cessation of vibration. Rather, to the extent that Tepic discloses the use of a vibratory force, this is addition to the pressure being applied to the piston (76) which is being advanced so as to deliver the cement to the target site. See column 10, lines 49 to 59, below.

In some applications, it may be desirable to subject
50 the cementitious material being applied to the patient's
implantation site to a vibratory force in addition to the
static pressure due to the advancing piston head 68. For
this, a conventional vibrating mechanism 106 is con-
nected via structure 78 to cap 42 as shown in FIG. 5 to
55 impart a vibratory motion, say, at 60 Hz, to the piston
rod 66 and its head 68. Accordingly, as the head ad-
vances to apply cement to the site, it applies a vibratory
force to the cement mixture MP in container 10 as it is
being extruded and which supplements the static force.

As can be seen with reference to the above, the vibratory force is applied to supplement the force being exerted on the piston to extrude the cement from its container. Accordingly, because the vibratory force is merely supplemental to the delivery force being applied to the piston, Tepic does not teach that penetration of the cement into the target bone site stops substantially simultaneously with cessation of vibration. As Ison was cited solely for its disclosure of calcium phosphate cements, it fails to remedy the deficiencies of Tepic and Li.

Therefore, a *prima facie* case of obviousness has not been established with respect to the claims as amended because the recited combination fails to teach every element of the rejected claims, namely, vibrating a cement composition as it is delivered to a target bone site in a manner such that penetration of the cement into the target bone site stops substantially simultaneously with cessation of vibration. In view of this, the Applicants respectfully request that 35 U.S.C. § 103(a) rejection of Claims 33, 34, 37, 38 and 42-46 be withdrawn.

Claims 33-45 and 47-54 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Karpman *et al.* (U.S. Patent No. 6,214,012) in view of Tepic (U.S. Patent No. 4,463,875) and Ison *et al.* (U.S. Patent No. 5,496,399).

As set forth above, a feature of Claim 33, as amended, is that a cement is vibrated as it is delivered to a target bone site in a manner such that penetration of the cement into the target bone site stops substantially simultaneously with cessation of vibration.

In rendering this rejection, the Office acknowledges that Karpman is deficient in that it fails to teach or suggest delivering a calcium phosphate cement by vibration of the cement as it is being delivered to the target bone site. Accordingly, the Office relies upon Tepic and Ison to remedy the deficiencies of Karpman.

The Applicants respectfully disagree to the extent that this rejection may be applied to the claims as amended. As described above, the use of the vibratory force, disclosed in Tepic, in conjunction with the delivery of a cement to a target site, is supplement to the force being exerted on a piston which is used to extrude the cement from its container. Accordingly, because the vibratory force is merely supplemental to the delivery force being applied to the piston, Tepic does not teach that penetration of the cement into the target bone site stops substantially simultaneously with cessation of vibration. As Ison was cited solely for its disclosure of calcium phosphate cements, it fails to remedy the deficiencies of Tepic and Karpman.

Therefore, a *prima facie* case of obviousness has not been established with respect to the claims as amended because the recited combination fails to teach every element of the rejected claims, namely, vibrating a cement composition as it is delivered to a target bone site in a manner such that penetration of the cement into the target bone site stops substantially simultaneously with cessation of vibration. In view of this, the Applicants respectfully request that 35 U.S.C. § 103(a) rejection of Claims 33-45 and 47-54 be withdrawn.

CONCLUSION

In view of the amendments and arguments above, Applicants respectfully submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at (650) 327 3400.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815.

Respectfully submitted,

Date: 10.23.06

By: _____


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